BACKGROUND INFORMATION ON THE PROCEDURE

1 Submission of the dossier

The applicant Schein Pharmaceuticals UK Ltd submitted on 6 December 2002 an application for Marketing Authorisation to the European Agency for the Evaluation of Medicinal Products (EMEA) for Oxybutynin Nicobrand, in accordance with the centralised procedure falling within the scope of Part B of the Annex to Council Regulation No (EEC) 2309/93 of 22 July 1993, as amended. On 9 September 2003 the EMEA was informed of a name change of the applicant from Schein Pharmaceutical UK Ltd to Nicobrand Limited.

The Rapporteur and Co-Rapporteur appointed by the CPMP were:

Rapporteur: Dr. Pieter Neels Co-Rapporteur: Prof. Cristina Sampaio

Scientific Advice:

The applicant did not seek scientific advice from the CPMP.

Licensing status:

Oxybutynin Nicobrand has been given a Marketing Authorisation in the USA on 03/03/2003. A new application is pending in Canada.

2 Steps taken for the assessment of the product

- The procedure started on 24 February 2003.
- The Rapporteur's first Assessment Report was circulated to all CPMP members on 9 May 2003. The Co-Rapporteur's first Assessment Report was circulated to all CPMP members on 6 May 2003.
- During the meeting on 26 June 2003, the CPMP agreed on the consolidated List of Questions to be sent to the applicant.
- The summary report of the inspection carried out at the manufacturing site of the finished product Watson Laboratories, Inc**,** Salt Lake City, Utah, USA, between 29-31 July 2003 was issued on 17 October 2003
- The applicant submitted the responses to the CPMP consolidated List of Questions on 9 September 2003.
- The Rapporteurs circulated the Joint Assessment Report on the applicant’s responses to the List of Questions to all CPMP members on 24 October 2003.
- Further to clarificatiom received from the Applicant on 11 November 2003, the Rapporteur and Co-rapporteur circulated an addendum to the Joint Assessment Report on 14 November 2003.
- During the meeting on 20 November 2003, the CPMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to Oxybutynin Nicobrand on 20 November 2003.
- The European Commission requested to reconsider this application according to a different legal basis and subsequently to revise the initial Opinion of 20 November 2003.
- During the meeting on 24-26 February 2004 the CPMP, in the light of the overall data and justifications submitted and the scientific discussion within the Committee, issued a revised positive Opinion for granting a Marketing Authorisation to Oxybutynin Nicobrand on 26 February 2004.